compositions, the non-sterile, sealed aerosol containers and the non-sterile first and second hermetically sealed container enclosures.

7. 35. The closed shipping package of claim 34 wherein said chemical composition is alcohol and said first and second hermetically sealed container enclosures consist of a single layer of a polyethylene plastic material.--

REMARKS

The Office Action dated September 11, 2002 has been carefully considered. In response thereto, the present application has been amended in a manner that is believed to significantly simplify the issues and place the application in condition for allowance. Accordingly, reconsideration of this application, withdrawal of the rejections and issuance of a Notice of Allowance are respectfully requested.

By this Amendment, claims 1-28 have been canceled and seven new claims 29-35, including independent claims 29, 33 and 34, have been added and are the only pending claims remaining in this application. Independent claim 29 is similar to canceled claim 20, but includes the step of transferring; independent claim 33 is similar to canceled claim 22, but includes the details of storing and opening in a non-sterile environment; and independent claim 34 is similar to canceled claim 23, but includes that the various elements are non-sterile. Attached hereto is a marked-up version of the changes made to the claims by the present amendment captioned "Version Showing Changes Made."

Before discussing the Office Action, it is appropriate to consider Applicant's invention and new claims 29-35 that more particularly point out the patentable features of Applicant's

invention. With respect to the method of sterilization, claim 29 more particularly defines the method in which all the steps of the method up to and including the final packaging of the double-bagged chemical composition container in a closed shipping package "under non-sterile conditions." The method then calls for the steps of "transferring said closed shipping package with its contents in a non-sterile condition to an irradiation plant" (see specification at page 16) where the closed cartons 36 are externally irradiated to simultaneously sterilize the double-bags, the container and the chemical composition contained therein.

Advantageously, all of the claimed method steps up to and including the final packaging in a closed carton for shipment involve non-sterile conditions so that there is no need to handle and package sterilized packages as is required by the cited prior art. Elimination of such handling advantageously eliminates the possibility of damage to the sterilized packages by reason of such handling. A further advantage of the claimed method is that only non-sterilized products need to be kept in inventory because the irradiation sterilization process can be carried out as part of the shipping process. For example, when a customer orders a sterilized chemical composition product, a closed shipping package containing one or more double-bagged, non-sterile containers of that product may be removed from inventory and sent to an irradiation plant (on or off premises) for irradiation sterilization and shipment to the customer.

Claim 30 is directed to the non-sterile packaging of a plurality of double-bagged chemical composition containers in a plurality of closed shipping packages; claim 31 specifies that the container is an aerosol container pressurized with an inert gas prior to sealing; and claim 32 specifies, using "consist" language rather than "comprise" language, that the "first and second sealing layers each *consist* of a single layer of a polyethylene plastic material." Those claims

further patentably distinguish the claimed sterilizing method over the prior art as explained more fully hereinafter.

Claim 33, directed to a method of storing a sterilized chemical composition, also recites the non-sterile condition of the contents of the closed shipping package and the irradiation sterilization of the contents of the closed shipping package.

Article claim 34 is directed to the closed shipping package with a plurality of non-sterile components "adapted to be externally radiated at a predetermined radiation level for a predetermined time interval to simultaneously sterilize the non-sterile chemical compositions, the non-sterile, sealed aerosol containers and the non-sterile first and second hermetically sealed container enclosures." Dependent article claim 35 specifies the chemical composition as alcohol and the first and second container enclosures as "consisting of" a single layer of a polyethylene.

Turning now to the Office Action, in view of the cancellation of claim 9, the Examiner's rejection of that claim under 35 U.S.C. §112, second paragraph is moot. All the original claims 1-28 were rejected by the Examiner under 35 U.S.C. §103 as unpatentable over either the *Clean Rooms Magazine* (Reader Service No. 498) excerpt or Falciani et al. ("Falciani") (U.S. Patent No. 4,700,838) in view of one or more of Falciani, Perlman (U.S. Patent No. 5,060,823), Anthony et al. ("Anthony") (U.S. Patent No. 4,714,595), Anderson (U.S. Patent No. 4,896,768) and Pomerantz et al. ("Pomerantz") (U.S. Patent No. 2,904,392).

At the outset, notwithstanding the cancellation of claims 1-28, the Applicant traverses all the prior art rejections made by the Examiner, but will specifically address only those combinations of prior art references that are arguably relevant to the new claims 29-35 presented herein. Thus, for example, in view of the cancellation of claims 15, 16, 27 and 28, the only claims to which the Anderson and Pomerantz references were applied by the Examiner, those

references are not addressed in the Remarks herein. However, the fact that each of the rejections of claims 1-28 and each cited prior art reference are not specifically addressed herein is not an admission by the Applicant that any of the Examiner's prior art rejections or combinations of references is correct.

Considering now the *Clean Rooms Magazine* (Reader Service No. 498) excerpt cited by the Examiner, the entire text of that excerpt is set forth hereinafter in order to show the brevity of the reference, to help explain the indefiniteness and ambiguity of the reference and as an aid to show that the Examiner's reading of the teachings of that reference are clouded by hindsight. Thus, the entire excerpt reads as follows:

> Sterile spray
>
> Veltek Associates, Exton, PA, offers Decon-Ahol Sterile which is a 70 percent or 91 percent filtered USP isopropyl alcohol aerosol spray. The spray can be used in decontamination operations.
>
> The spray is packaged in a double bag sterile pack for introduction into the sterile area. The spray is terminally sterilized, documented and validated according to the company.
>
> Reader Service No. 498

At page 3 of the Office Action, the Examiner states:

> The excerpt from *Clean Rooms Magazine* teaches that it was known in the art at the time the invention was made to package an aerosol solution in an aerosol container (which by definition is pressurized), double bag the container in a sterile pack (e.g. hermetically sealed), and terminally sterilize the resulting pack.

In Applicant's prior application Serial No. 09/627,398, the Examiner also considered the *Clean Rooms Magazine* excerpt and correctly concluded that "[t]he excerpt from *Clean Rooms*

Magazine does not teach pressurizing the internal volume of the container with an inert gas . . . ." Office Action dated August 16, 2001. That position of the Examiner with respect to the *Clean Rooms Magazine* excerpt is correct because the excerpt does not mention any type of "container" whatsoever, much less an "aerosol container" as asserted by the Examiner in the present Office Action. It is well known in the art that an "aerosol spray" can be generated by any type of spray bottle, including trigger spray bottles and other types of non-pressurized bottles or containers, as well as "aerosol bombs," as pressurized aerosol containers are known in the art. *See also* the other *Clean Rooms Magazine* excerpt, Reader Service No. 419 (Reference AW or AY), which refers to an "aerosol spray" in the form of a "stream spray or mist spray," the "stream spray" being atypical of a pressurized aerosol bomb.

Accordingly, with respect to pressurization, the Examiner correctly interpreted the *Clean Rooms Magazine* excerpt Reader Service No. 498 in the Office Action dated August 16, 2001 in Serial No. 09/627,398 and incorrectly interpreted that reference in the Office Action in this application. In sum, the *Clean Rooms Magazine* excerpt is simply ambiguous and non-enabling with respect to the type of receptacle used to contain the "spray." Consequently, the Clean Rooms Magazine does not teach or suggest to one of ordinary skill in the art to use a pressurized container, as provided for in the claimed invention. Absent a teaching, the Examiner is without basis to conclude that it would be obvious to one of ordinary skill in the art to use a pressurized container.

In addition, the *Clean Rooms Magazine* excerpt is also ambiguous and non-enabling with respect to the point or points at which the "aerosol spray" is sterilized. The excerpt states that "[t]he spray is packaged in a double bag sterile pack . . ." and thus teaches that the double bags are sterile when the "spray" is packaged in them. The excerpt statement that "[t]he spray is

terminally sterilized . . . " suggests that a final sterilization step is used to somehow sterilize or resterilize the spray. Of course, it is easy in hindsight to attribute an interpretation to the words of the excerpt consistent with the teachings of Applicant's invention. However, the excerpt must be interpreted without regard for the teachings of Applicant's invention; otherwise the interpretation is erroneous.

In any event, there is no teaching in the *Clean Rooms Magazine* excerpt that the double bags are "non-sterile" when the aerosol spray (presumably contained in some undisclosed receptacle form) is packaged in the bags. Moreover, even assuming *arguendo* that the *Clean Rooms Magazine* excerpt suggests sterilization of a spray contained in a receptacle in its double-bagged configuration ("terminal sterilization"), the excerpt does not teach or suggest sterilization after the double bag configuration has been placed in a shipping carton and the carton has been closed for shipment as recited in the new claims submitted in this Amendment.

As the Examiner must agree, despite her assertions that "terminal sterilization" is taught by the *Clean Rooms Magazine* excerpt, and by Perlman, Anthony and Anderson, not one of those references teaches sterilization of a final, closed shipping package that has been packaged under non-sterile conditions so that, prior to sterilization, it contains one or a plurality of non-sterile, double-bagged containers of a non-sterile chemical composition. Nor do those references teach transferring the aforesaid closed shipping package with its non-sterile contents to an irradiation plant for irradiation sterilization of those contents. Indeed, all the cited references, including the *Clean Rooms Magazine* excerpt (even as read in hindsight), teach either packaging under sterile conditions (Falciani) or sterilization of an individual container *before it is enclosed in a final closed shipping package* (*Clean Rooms Magazine* excerpt, Perlman, Anthony and Anderson).

Only Falciani teaches placing a plurality of bags in a shipping package, namely, a polystyrene case and a corrugated cardboard box. *See* Falciani at col. 3, lines 15-21. However, Falciani's bags and their contents are sterilized prior to placing them in the shipping package and thus Falciani teaches away from Applicant's invention as embodied in new claims 29-35. Even assuming *arguendo* the *Clean Rooms Magazine* excerpt, Perlman, Anthony or Anderson could be properly combined with Falciani and used for their teachings of "terminal sterilization," the clear teachings and/or suggestions of all the applied references are to sterilize individual double-bagged containers prior to placing them in a final shipping package and closing it.

With reference to claims 31 and 34, the fact that (contrary to the most recent position of the Examiner as set forth on page 3 of the Office Action) the *Clean Rooms Magazine* excerpt does not teach a pressurized aerosol container makes the basis for the Examiner's combination of the *Clean Rooms Magazine* excerpt with Perlman more tenuous, especially since Perlman's pressurized aerosol can is intended only for sterile delivery of a liquid (a cell culture-related solution) and is not intended to be used in a sterile environment as is the spray of the *Clean Rooms Magazine* excerpt.

As to claims 32 and 35 directed to the polyethylene material used for the first and second hermetically sealed bags, those claims require that each bag have only one polyethylene layer and thus distinguish over Falciani and Anthony, both of which require that one of the enclosing bags be a multi-layer composite bag. *See e.g.*, Falciani at col. 3, lines 8-14 and claim 1 and Anthony at col. 6, line 65 to col. 7, line 10.

For all the foregoing reasons, and in view of the new claims 29-35 submitted in this Amendment, reconsideration of this application and allowance of the claims are respectfully requested.

In the event there are any questions relating to this Amendment or to the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Please charge any shortage or credit any overpayment of fees to BLANK ROME COMISKY & McCAULEY LLP, Deposit Account No. 23-2185 (100858.00106). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this response, Applicant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to render this submission timely. Any fee due is authorized above.

Respectfully submitted,

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VERSION SHOWING CHANGES MADE

IN THE CLAIMS:

Claims 1-28 have been cancelled and new claims 29-35 have been added, as follows:

--29. A method of sterilizing a chemical composition contained in a sealed container comprising the steps of, under non-sterile conditions:

providing a container having an internal volume;

charging the internal volume of the container with a quantity of chemical composition;

sealing the internal volume of the container to form a sealed container;

hermetically heat sealing the container in a first sealing layer to form a first hermetically heat-sealed container enclosure;

hermetically heat sealing said first hermetically sealed container enclosure in a second sealing layer to form a second hermetically heat-sealed container enclosure;

enclosing said second hermetically heat-sealed container enclosure in a shipping carton to form a closed shipping package the contents of which include said chemical composition, said sealed container, and said first and second hermetically heat-sealed container enclosures;

transferring said closed shipping package with its contents in a non-sterile condition to an irradiation plant; and

externally irradiating said closed shipping package and its contents at the irradiation plant at a predetermined radiation level for a predetermined time interval to simultaneously sterilize

said chemical composition, said sealed container, and said first and second hermetically heat-sealed container enclosures.

30. The method of claim 29 comprising enclosing a plurality of said second hermetically heat-sealed container enclosures in each of a plurality of said shipping cartons to form a plurality of closed shipping packages, transferring said plurality of closed shipping packages and their contents in a non-sterile condition to an irradiation plant, and externally irradiating said closed shipping packages and their contents at the irradiation plant at a predetermined radiation level for a predetermined time interval to simultaneously sterilize the chemical compositions, the sealed containers, and the first and second hermetically heat-sealed container enclosures contained in each closed shipping package.

31. The method of claim 30 wherein each container is an aerosol container and including the step of pressurizing the internal volume of each aerosol container with an inert gas prior to sealing each container.

32. The method of claim 29 wherein said first and second sealing layers each consist of a single layer of a polyethylene plastic material.

33. A method of storing a sterilized chemical composition and maintaining the sterilization shelf life of the sterilized chemical composition for a prolonged period of time, said sterilized chemical composition being contained in a plurality of sealed containers, each sealed container being hermetically sealed in a first hermetically sealed container enclosure, each first

hermetically sealed container enclosure containing a sealed container being hermetically sealed in a second hermetically sealed container enclosure, a plurality of the second hermetically sealed container enclosures each containing a first hermetically sealed container enclosure and a sealed container being enclosed in a shipping enclosure to form a closed shipping package the contents of which have been sterilized by radiation at an irradiation plant and transported to a storage area for operational use, comprising the steps of:

opening the closed shipping package and removing the sterilized second hermetically sealed container enclosures each containing a sterilized sealed container and a sterilized first hermetically sealed container enclosure from the closed shipping package;

storing the sterilized second hermetically sealed container enclosures each containing a sterilized sealed container and a sterilized first hermetically sealed container enclosure in the storage area for a period of time;

after the period of time, removing at least one of the sterilized second hermetically sealed container enclosures from the storage area, opening the removed second hermetically sealed container enclosure and transporting the sterilized first hermetically sealed container enclosure containing the sterilized sealed container to a sterile environment; and

opening the sterilized first hermetically sealed container enclosure in the sterile environment and removing the sterilized sealed container from the sterilized first hermetically sealed container enclosure for use of the sterilized chemical composition in the sterile environment.

34. A closed shipping package adapted to be terminally sterilized with radiation comprising a plurality of non-sterile, sealed aerosol containers each having an internal volume

and being charged with a quantity of a chemical composition and pressurized with an inert gas, a non-sterile first hermetically sealed container enclosure hermetically sealing each aerosol container, a non-sterile second hermetically sealed container enclosure hermetically sealing each first hermetically sealed container enclosure, each non-sterile second hermetically sealed container enclosure containing a non-sterile, sealed aerosol container contained within a non-sterile first hermetically sealed container enclosure, and a shipping carton enclosing a plurality of the non-sterile second hermetically sealed container enclosures to form a non-sterile closed shipping package, the non-sterile closed shipping package externally radiated at a predetermined radiation level for a predetermined time interval to simultaneously sterilize the chemical compositions, the non-sterile, sealed aerosol containers and the non-sterile first and second hermetically sealed container enclosures.

35. The closed shipping package of claim 34 wherein said chemical composition is alcohol and said first and second hermetically sealed container enclosures consist of a single layer of a polyethylene plastic material.--